US ERA ARCHIVE DOCUMENT

Memorandum

Date: 27 April 1982

Subject: EPA Reg. No. 476-1991 STAUFFER ASPON 2-E

Caswell 845A

From: B. 7

B. T. Backus

IRB/TSS

To:

Mr. William Miller Product Manager 16

Registrant: Stauffer Chemical Co.

1200 South 47th St. Richmond, CA 94804

Active Ingredient:

Background:

The registrant has submitted Acute Oral LD50, Dermal LD50, Primary Dermal and Eye Irritation studies on this formulation as data required to support its reregistration.

Comments and Recommendations:

- 1. The Acute Oral LD50, Dermal LD50, Primary Dermal and Eye Irritation studies received 3-4-82 on this product are acceptable.
- A short summary of an Acute Inhalation LC50 study was submitted, but the actual study was not received. According to the summary sheet, this study is in final report preparation.

Labeling:

- 1. "Atropine by injection is antidotal" should be revised to "Atropine by injection is antidotal only if symptoms of cholinesterase inhibition are present."
- 2. According to the Confidential Statement of Formula, this product contains a considerable amount of xylene range aromatic solvent. As noted by Gosselin et al. (Clinical Toxicology of Commercial Products, 4th edition, Section III, p. 320): "...a strong likelihood exists that an acute chemical pneumonitis can be precipitated by the aspiration of ingested aromatic hydrocarbon solvents..." For this reason, induction of vomiting is not recommended, and the IF SWALLOWED statement of practical treatment should be revised to something like the following:

IF SWALLOWED: Contact your local Poison Control Center, physician or hospital immediately. Do Not Induce Vomiting! If the patient is unconscious, maintain breathing and heart rate (CPR: cardiopulmonary resuscitation).

3. The Statement of Practical Treatment for IF ON SKIN should be:

IF ON SKIN: Wash with plenty of soap and water.

(although not necessary, we can accept the additional wording: "Remove contaminated clothing and shoes. Get medical attention if irritation occurs. Wash clothing before re-use.").

4. The Statement of Practical Treatment for IF IN EYES could be something like:

IF IN EYES: Flush with water for 15 minutes. Get medical attention.

alternatively, we can accept the statement proposed in the labeling received 3-4-82, although we would prefer IF IN EYES to FOR EYE CONTACT.

5. The recommended Statement of Practical Treatment IF INHALED is:

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth.

Get medical attention.

6. The Hazards to Humans and Domestic Animals statement should be:

WARNING: Causes eye irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed or absorbed through skin.

Avoid breathing spray mist. Wash thoroughly after handling.

Avoid contamination of food and forage crops.

Review:

The following studies were conducted on a representative sample (containing 26.3% active; label declaration = 25.67%) of the registered product. Studies were conducted at the Stauffer Chemical Company Richmond Toxicology Laboratory, Richmond, CA 94804 under Laboratory Report T-10331. Studies were received at EPA 3-4-82, and are in Acc. 246890.

1. Acute Oral LD50 - Rat. Laboratory Report T-10331; dated 10-7-81.

Procedure: Groups of 10M SD rats received oral dosages of 3162, 3548, 3981 or

5000 mg/kg. Groups of 10F SD rats received oral dosages of 1259, 1585, 1995 or 2500 mg/kg. Subjects were observed for 14 days.

Results: Mortalities:	Mortalities/Animals	Dosed
Dosage Level (mg/kg)	M	F
1259	-	5/10
1585	-	6/10
1995	-	9/10
2500	-	9/10
3162	3/10	_
3548	8/10	-
3981	8/10	-
5000	10/10	_

Oral LD50 (M) = 3260 (2950-3603) mg/kg. Oral LD50 (F) = 1350 (1120-1628) mg/kg.

Symptoms: depression, ruffled fur, diarrhea, shallow and/or labored respiration, salivation, occasional tremors, chromodacryorrhea, ano-genital staining.

Necropsies of mortalities showed yellowish-red intestines, reddened lungs, mottled livers. 14-day survivors were, on post-sacrifice necropsies, unremarkable.

Study Classification: Core Minimum Data (no individual body weight data, lowest dosage level at which females were tested had 50% mortality).

Product Classification: Tox. Cat. III

2. Acute Dermal LD50 - Rabbit. Laboratory Report T-10331; dated 10-7-81.

<u>Procedure</u>: A group of 10 Stauffland albino rabbits, with at least 4M, 4F, received a 24-hr occluded dermal exposure to a dosage level of 2000 mg/kg with subsequent 14-day observation.

Results: No mortalities. No symptoms. Post-sacrifice necropsies were unremarkable.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

3. Primary Dermal Irritation - Rabbit. Laboratory Report T-10331; dated 10-7-81.

<u>Procedure</u>: 0.5 mls was placed at each of 2 sites, one intact, one abraded, on each of 6 rabbits, with 24-hr occluded dermal exposure.

<u>Results</u>: PDIS = 1.5. Some minimal edema (score=1) seen at 72 hrs where there had been none at 24 hrs. Erythema scores at 24 and 72 hrs ranged from 1-2.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

4. Primary Eye Irritation - Rabbit. Laboratory Report T-10331; dated 10-7-81.

<u>Procedure</u>: 0.1 mls test material was placed in one eye of each of 9 rabbits, with 3 eyes being flushed with water starting 20-30 seconds after instillation. Remaining 6 eyes were unwashed.

Results: All eyes had some irritation at 24 hrs; (only total Draize scores given). One rabbit with an unwashed eye obviously had corneal opacity persisting through 21 days. Other 8 rabbits all scored zero by 7 days.

Study was repeated:

<u>Results</u>: All eyes had some irritation at 24 hrs; three unwashed eyes had positive scores by day 7, including 2 in which there was probably some corneal opacity. All eyes scored zero at 14 days.

Study Classification: Core Minimum Data

<u>Product Classification:</u> Tox. Cat. II

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Byron T. Backus

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